REMARKS/ARGUMENTS

Claims 1-4, 7 and 10-23 are pending, claims 14-23 having been withdrawn from consideration. By this Amendment, claims 5, 6, 8 and 9 are cancelled, and claims 1 and 14-23 are amended. Support for the amendments to claims 1 and 14-23 can be found, for example, in the present specification at page 8, lines 18 to 20, and in original claims 1, 5, 6, 8, 9 and 14-23. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Withdrawn Claims

For the reasons set forth below, Applicants submit that all pending claims presently subject to examination are in condition for allowance. Because the withdrawn claims depend from, and thus recite all features of, allowable claim 1, rejoinder and allowance of the withdrawn claims are respectfully requested.

Objection to the Specification

The Office Action objects to the specification as having been amended to include new matter. Applicants submit that this objection is made in error. Applicants did not amend the specification in the July 18, 2008 Amendment – the Amendment includes no indications or instructions to amend the specification. Rather, Applicants submitted an English-language translation of the provisional application to which the present application claims priority. Any alleged differences between the provisional application and the present application can not constitute new matter, as the applications are separate applications. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

Rejection Under 35 U.S.C. §102

The Office Action rejects claims 1-9 and 13 under 35 U.S.C. §102(b) over U.S. Patent Application Publication No. US 2002/0047058 to Verhoff et al. ("Verhoff"). By this Amendment, claims 5, 6, 8 and 9 are cancelled, rendering the rejection moot as to those claims. As to the remaining claims, Applicants respectfully traverse the rejection.

Claim 1 recites "[a] composition, comprising: a very low water-soluble drug; and a porous material; wherein: the composition is produced by treating a mixture comprising the very low water-soluble drug and the porous material with a supercritical or subcritical carbon dioxide fluid; the very low water-soluble drug has a solubility in water at 25 °C of less than 10 μg/mL prior to treatment; the porous material is not a porous silica material having an average pore diameter of 1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of ± 40% of the average pore diameter accounts for 60% or more of a volume of all of the pores of the porous material, and having an X-ray diffraction pattern including one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more; the porous material has an average pore diameter of 1 to 500 nm; and the porous material has a specific surface area of 100 to 1,800 m^2/g" (emphasis added). Verhoff does not disclose or suggest such a composition.

As indicated above, the porous material of the composition of claim 1 has an average pore diameter of 1 to 500 nm and a specific surface area of 100 to 1,800 m^2/g. Verhoff does not disclose employing a porous material having such characteristics. Instead, Verhoff discloses employing the product Nyacol 9950 as a silica material. *See, e.g.,* Verhoff, paragraph [0293]. Applicants have attached hereto product information for Bindzil 9950, which is the present trade name for Nyacol 9950.[#] As is evident from the product

[#] Applicants have attached hereto a letter from Eka Chemicals and a partial English-language translation thereof confirming that the product identified as Nyacol 9950 in Verhoff is presently known as Bindzil 9950.

information for Bindzil 9950, Nyacol 9950 as employed in Verhoff has a specific surface area of 80 m^2/g, which falls outside the scope required in claim 1. That is, Verhoff fails to disclose employing a porous material as recited in claim 1.

The Office Action appears to assert that it would have been obvious to select, e.g., a particular average pore diameter or a particular specific surface area for the porous materials employed in Verhoff. *See* Office Action, page 6. As is well-settled, a particular parameter must first be recognized as a result-effective variable before the determination of workable ranges can be said to be an obvious variation. *See, e.g.,* MPEP §2144.05.II.B (citing *In re Antonie*, 195 U.S.P.Q. 6 (C.C.P.A. 1977)). The Office Action fails to identify, in any of the cited references, recognition that average pore diameter or specific surface area are result-effective variables. Absent such recognition, one of ordinary skill in the art would not have had a reasonable expectation of success upon manipulating the average pore diameter or specific surface area of the porous materials of Verhoff – one of ordinary skill in the art would not have been motivated to optimize those variables, as asserted by the Office Action.

For the reasons discussed above, a *prima facie* case of obviousness can not be made. However, even if a *prima facie* case were made, such case is rebutted by the results shown in the present specification and the Declaration Under 37 C.F.R. §1.132 ("Declaration") attached hereto – "[a] *prima facie* case of obviousness ... is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties." *See* MPEP §2144.09 (citing *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963)). Applicants have undertaken additional experimentation, which demonstrates that compositions including a porous material having the characteristics required by claim 1 provide unexpected, superior results in comparison with otherwise identical compositions that employ non-porous materials or porous material that do not have the characteristics required by claim 1.

Accordingly, the product information relating to Bindzil 9950 accurately describes the characteristics of the Nyacol 9950 used in Verhoff.

As is evident from the results shown in the TABLE in the Declaration, subjecting a very low water-soluble drug and either a non-porous material or a porous material not having the particular average pore diameter and specific surface area of claim 1 to treatment with a supercritical or subcritical carbon dioxide fluid, does not result in improved solubility of the very low water-soluble drug in comparison with the improved solubility of the compositions according to claim 1. *See* Declaration, paragraphs 6 and 7; present specification, Table 1. The improved performance exhibited by compositions according to claim 1 of the above-captioned patent application, relative to compositions disclosed or suggested by Verhoff, is significant and unexpected. *See* Declaration, paragraph 7. These results are objective evidence of the improvements of the composition of claim 1 over known compositions as in Verhoff, and thus these results rebut any suggestion that it would have been obvious to modify the compositions of Verhoff to obtain the compositions of claim 1.

While not emphasized in the discussion above, the Office Action asserts that the recitation of "by treating a mixture comprising the very low water-soluble drug and the porous material with a supercritical or subcritical carbon dioxide fluid" in claim 1 is product-by-process language that should not be given weight. *See* Office Action, pages 5 to 6. Applicants submit that the experimental evidence in the present specification clearly demonstrates that the process step recited in claim 1 confers unique properties (e.g., solubility) to the resulting product. The Office Action is requested to provide a basis for ignoring the experimental data in the present specification demonstrating that the properties of products obtained as recited in claim 1 are different from products obtained otherwise.

As explained, claim 1 is not anticipated by Verhoff. Claims 2-4, 7 and 13 depend from claim 1 and, thus, also are not anticipated by Verhoff. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1-13 under 35 U.S.C. §103(a) over Verhoff in view of U.S. Patent No. 5,538,728 to Yanaki et al. ("Yanaki"). By this Amendment, claims 5, 6, 8 and 9 are cancelled, rendering the rejection moot as to those claims. As to the remaining claims, Applicants respectfully traverse the rejection.

For the reasons discussed above, Verhoff fails to disclose or suggest each and every feature of claim 1. Yanaki does not remedy the deficiencies of Verhoff. Yanaki is cited for its alleged disclosure of a pharmaceutical composition including a complex of a water-swellable silicate mineral and a drug. *See* Office Action, page 9. However, Yanaki, like Verhoff fails to disclose or suggest a composition including a porous material having an average pore diameter of 1 to 500 nm and a specific surface area of 100 to 1,800 m^2/g. Accordingly, the combination of references fails to disclose or suggest each and every feature of claim 1.

As explained, claim 1 would not have been rendered obvious by Verhoff and Yanaki. Claims 2-4, 7 and 10-13 depend from claim 1 and, thus, also would not have been rendered obvious by Verhoff and Yanaki. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 1-4, 7 and 10-23 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

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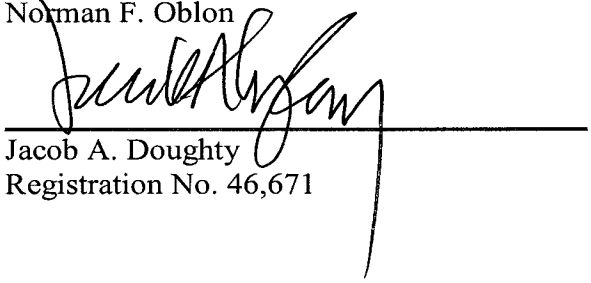
MAIER & NEUSTADT, P.C.
Norman F. Oblon



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Attachments:
Letter from Eka Chemicals and Partial English-Language Translation
Product Information for Bindzil 9950
Declaration Under 37 C.F.R. §1.132